PSJ3

Exhibit 674B

The American Alliance of Cancer Pain Initiatives Statement on State Prescription Monitoring Programs

June 2002

The American Alliance of Cancer Pain Initiatives (AACPI) is dedicated to the prevention and optimal treatment of cancer pain. Many individuals with cancer-related pain require opioid analgesics to achieve adequate pain control. While these medications are extremely beneficial to many individuals, they can be abused. The AACPI recognizes the dual nature of these substances, and is committed to assuring their availability for legitimate medical purposes as well as to preventing their diversion and abuse.

A number of states have developed prescription monitoring programs (PMPs) to prevent and detect the abuse and diversion of controlled substances.[19] PMPs address abuse and diversion from only one source, namely, healthcare providers' prescription of medications to patients.[17] PMPs are not intended to interfere with appropriate medical practice and the optimal relief of pain.[16,18,21] However, physicians express concern about the possibility of legal, regulatory, or administrative sanctions resulting from the increased monitoring of their prescriptions.[5,15] As a result they may be less likely to prescribe opioids, which may result in less than optimal pain management. Unfortunately, there has as yet been little research to examine the impact of PMPs on physician prescribing, pain management, or drug diversion and abuse.[1,2,6,10,11,14]

The nature and extent to which controlled substances are abused and diverted vary from state to state. Data that are currently available from a variety of sources, including pharmacy theft reports, Medicaid Drug Utilization Review programs, existing PMPs, and others, can be tremendously helpful to states in their efforts to identify sources of diversion.[3,8,9,13] These data sources should be utilized to their fullest extent before any consideration is given to the implementation of new programs.[4,7,20]

Recent events have created a sharp increase in interest in PMPs among legislators, regulators, and other policy leaders in a number of states. The AACPI does not oppose the establishment of these programs *per se*. However, it believes that no new PMPs should be established until and unless existing information sources have been fully utilized. The AACPI encourages relevant authorities in the various states to adopt balanced approaches that address all sources of diversion while not interfering with the use of controlled substance for legitimate medical purposes. The AACPI suggests that such balanced approaches include the following:

1) States should consider adopting the 1994 Uniform Controlled Substances Act provision (Section 309) [12] establishing an interagency diversion prevention and control program to coordinate the use of different sources of information and the cooperation of various government authorities;

2) If a prescription monitoring program is considered for adoption, the following characteristics are recommended:
   a) Use of government-issued multiple-copy or single-copy serialized prescription forms should be avoided;
   b) All controlled substances in Schedules II, III, and IV under both federal and state law should be included;
   c) Such programs should be administered by the state agency responsible for regulating health care, rather than by the agency responsible enforcing the laws of the state;
   d) Assurances should be given that legitimate prescribing and dispensing is protected, through the use of a multidisciplinary medical review group. A medical review group could serve the following specific functions:
      i) Supervision of the management and uses of data collected by the PMP;
      ii) Development and review of mechanisms to facilitate effective and efficient means of targeting suspicious prescribing and dispensing patterns;
      iii) Review of individual healthcare providers' prescribing practices to assist in determining if they are participants in drug abuse or diversion;
      iv) Review of individual patient data to assist in differentiating between people with inadequately treated pain and people seeking drugs for abuse and/or diversion; and
      v) Oversight of the preparation and dissemination of annual data-based performance reports;
   e) Patient confidentiality should be protected to the greatest extent possible;
   f) Individual healthcare professionals should have access to PMP data concerning their individual patients for purposes of evaluating those patients' use of controlled substances;
   g) Law enforcement agencies should have access to the data when probable cause justifies such access in the course of investigating possible abuse or diversion;
3) Educational programs should be developed to address healthcare professionals' perceptions about PMPs. These programs should be jointly developed and sponsored by all relevant regulatory agencies, and should seek to minimize concern about regulatory scrutiny when prescribing or dispensing controlled substances as part of legitimate medical practice;
4) Healthcare professionals should be encouraged to communicate with their state PMP administrators if they have questions or concerns. In this way, they can minimize their concerns about regulatory scrutiny when prescribing or dispensing controlled substances as part of legitimate medical practice.

Further, the AACPI strongly urges the appropriate regulatory agencies to support and engage in research designed to evaluate the impact of PMPs on both patients needing controlled substances for legitimate medical purposes and the prevalence and incidence of drug abuse and diversion. It is only through such efforts that an accurate evaluation of the success of PMPs in achieving a balanced approach can be made.

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*The **American Alliance of Cancer Pain Initiatives** is a leading national nonprofit organization dedicated to improving cancer pain management. The AACPI is a grassroots network of state, regional and Native American Pain Initiatives — voluntary organizations composed of healthcare professionals, researchers, educators and patient advocates. By united persons from different disciplines and backgrounds, Cancer Pain Initiatives are removing the barriers that impede effective pain relief through education, advocacy, and institutional and practice change. For more information call 608-265-4013 or visit www.aacpi.org.*

References

(1) Sigler KA, Guernsey BG, Ingrim NB, Buesing AS, Hokanson JA, Galvan E et al. Effect of a triplicate prescription law on prescribing of Schedule II drugs. Am J Hosp Pharm 1984; 41:108-111.

(2) Berina LF, Guernsey BG, Hokanson JA, Doutre WH, Fuller LE. Physician perception of a triplicate prescription law. Am J Hosp Pharm 1985; 42:857-859.

(3) United States General Accounting Office. Controlled substances: medicaid data may be useful for monitoring diversion. GAO/HRD-88-111. Washington, D.C.: United States General Accounting Office, 1988.

(4) Joranson DE. Responding to prescription drug abuse. Cancer Pain Release 1989; 3(1):1.

(5) National Conference of Commissioners on Uniform State Laws. Uniform Controlled Substances Act. Adopted at its Annual Conference Meeting in its Ninety-Ninth Year; Milwaukee, WI; July 13-20, 1990. 1990. Chicago, IL, NCCUSL.

(6) Weintraub M, Singh S, Byrne L, Maharaj K, Guttmacher L. Consequences of the 1989 New York State Triplicate Benzodiazepine Prescription Regulations. JAMA 1991; 266(17):2392-2397.

(7) Collins TM, Zimmerman DR. Programs for monitoring inappropriate prescribing of controlled drugs: evaluation and recommendations. Am J Hosp Pharm 1992; 49:1765-1768.

(8) United States General Accounting Office. Prescription drug monitoring: states can readily identify illegal sales and use of controlled substances. GAO/HRD-92-115. Washington, D.C.: United States General Accounting Office, 1992.

(9) United States General Accounting Office. Medicaid prescription drug diversion: a major problem, but state approaches offer some promise. GAO/T-HRD-92-48. Washington, D.C.: United States General Accounting Office, 1992.

(10) Cooper JR, Czechowicz DJ, Molinari SP, Petersen RC. Impact of prescription drug diversion control systems on medical practice and patient care. NIDA research monograph 131. Rockville, MD: National Institute on Drug Abuse, 1993.

(11) Wastila LJ. The influence of multiple copy prescription programs (MCPPs) on analgesic utilization. 1993.

(12) National Conference of Commissioners on Uniform State Laws. Uniform Controlled Substances Act. Adopted at its Annual Conference Meeting in its One-Hundred-and-Third-Year; Chicago, IL; July 29-August 5, 1994. 1994. Chicago, IL, NCCUSL.

(13) United States General Accounting Office. Prescription drugs and medicaid: automated review systems can help promote safety, save money. GAO/AIMD-96-72. Washington, D.C.: United States General Accounting Office, 1996.

(14) Wastila LJ, Bishop C. The influence of multiple copy prescription programs on analgesic utilization. J Pharm Care Pain Symptom Control 1996; 4(3):3-19.

(15) Institute of Medicine Committee on Care at the End of Life. Approaching death: improving care at the end of life. Washington, D.C.: National Academy Press, 1997.

(16) Drug Enforcement Administration - Office of Diversion Control. Prescription accountability resource guide. Washington, D.C.: Drug Enforcement Administration, 1998.

(17) Alliance of States with Prescription Monitoring Programs. The goals of prescription monitoring. Jamaica Plain, MA: Massachusetts Department of Health, Drug Control Program, 1999.

(18) Drug Enforcement Administration, National Alliance for Model State Drug Laws. Diversion and abuse of prescription drugs: a closer look at state prescription monitoring programs. Washington, D.C.: Drug Enforcement Administration, 2000.

(19) Alliance of States with Prescription Monitoring Programs. States with prescription monitoring programs. National Association of State Controlled Substances Authorities website, 2001.

(20) Cancer Pain Management Policy Review Group. American Cancer Society position statement on prescription monitoring and drug utilization review programs. Atlanta, GA: American Cancer Society, 2001.

(21) Joranson DE, Carrow GM, Ryan KM, Schaefer L, Gilson AM, Good P et al. Pain management and prescription monitoring. J Pain Symptom Manage 2002; 23(3):231-238.

The American Alliance of Cancer Pain Initiatives Statement on Intractable Pain Treatment Acts (IPTA)

October 2003

The American Alliance of Cancer Pain Initiatives (AACPI) is dedicated to the prevention and optimal treatment of cancer pain. As part of its mission to ensure that individuals with cancer receive appropriate pain management, the AACPI works to remove and/or minimize the barriers that prevent such individuals from receiving optimal care.

Healthcare professionals in many states perceive that regulatory boards and law enforcement agencies are overzealous in disciplining practitioners who use opioids to treat pain. As a consequence, advocates for pain management have promoted the adoption of legislation designed to protect physicians who treat patients with "intractable pain." These statutes, known collectively as Intractable Pain Treatment Acts (IPTAs) have, to date, been adopted by 12 states.[1] One state, New Mexico, has adopted a similar statute which is known as a Pain Relief Act.

In recent years, there has been a significant increase in the numbers of statutes, regulations, and guidelines related to pain management. Nevertheless, there continues to be a perception in some states, that healthcare professionals need even greater protection from disciplinary actions and as a result a renewed interest in IPTA legislation. While these statutes are intended to protect physicians from inappropriate disciplinary actions they often contain features that are problematic.[2,3]

The AACPI does not support the introduction or adoption of additional IPTAs in the states, but suggests consideration of some other approach. However, if faced with such legislation, the AACPI suggests that individual State Pain Initiatives give careful consideration to the following:

1) Definition of "intractable pain": In general, intractable pain is defined in these statutes as "a pain state in which the cause of the pain cannot be removed or otherwise treated and in which, in the generally accepted course of medical practice, no relief or cure of the cause of the pain is possible, or none has been found after reasonable efforts." This definition implies that some individuals may develop pain that cannot be treated. In addition, by using this terminology, IPTAs exclude individuals with acute pain, as well as those who may choose not to pursue

potentially curative treatment for a condition causing pain. Finally, this definition requires that the physician "prove a negative;" that is, the physician must prove that there is NOT a treatable cause for the pain, or that the pain does NOT respond to treatment. Meeting such a requirement is impossible.

The AACPI suggests that the term "intractable pain" be avoided for these reasons. While some statutes, regulations, and guidelines use the term "chronic pain" instead of "intractable pain," the AACPI does not feel this is acceptable, because of the exclusions mentioned above. The preference would be to use the term "pain" without further qualification.

2) Requirement for consultation: Some IPTAs require, as part of the diagnosis of "intractable pain," that a specialist in the organ system perceived to be the source of the pain confirm the diagnosis through an evaluation. This requirement creates further barriers to care for individuals with pain. Such consultants may not be readily available in some areas, making it necessary for the affected individual to travel long distances for consultation. Furthermore, a specialist in the organ system perceived to be involved does not necessarily have expertise in pain assessment and management. In other situations, such consultations may fall outside an individual's insurance plan, and thus be prohibitively expensive. Finally, such a requirement necessitates additional delays prior to the initiation of treatment.

AACPI suggests that requirements for consultation be omitted.

3) Implication that opioids are the last resort: As seen in the definition of "intractable pain," for a physician to qualify for protection under an IPTA statute, a potentially extensive series of diagnostic and/or treatment procedures must be undertaken. There is nothing in these statutes that states that physicians are allowed to treat the individual's pain with opioids prior to reaching the conclusion that the patient has "intractable pain." Thus, treatment would be delayed for individuals who may eventually qualify under the statute.

The AACPI suggests that any proposed legislation recognize the right of individuals to receive treatment for pain whenever it is reported as a symptom, rather having treatment delayed until all other avenues have been exhausted.

4) Restriction of medical decision-making: The requirement that physicians establish that the cause of pain cannot be treated or removed, or that no relief or cure of the cause of pain is possible, unnecessarily restricts the decision-making authority of physicians. Physicians are trained to recognize symptoms and to treat those symptoms appropriately, even while they are making a diagnosis. They are trained to use whatever means they judge to be safe and effective in treating these symptoms. IPTAs, by requiring that physicians take a number of steps prior to benefiting from the IPTA, unduly restrict the ability of physicians to decide upon the appropriate treatment for their patients.

AACPI suggests that the language of any proposed legislation recognize the ability of physicians to diagnose and treat symptoms such as pain, and that any language that might restrict the options available be avoided.

5) Exclusion of "mid-level" providers: Of the 12 existing IPTAs, only one provides protection for healthcare professionals who are not physicians. Increasingly, advanced practice nurses and physician assistants are being granted the authority to prescribe medications (including opioids) for the treatment of pain and other symptoms. Furthermore, IPTAs typically protect physicians who "prescribe or administer" controlled substances, while excluding the nurses who, in fact, do the bulk of drug administration. In addition, other professions with long-recognized prescription privileges, such as dentists, are excluded.

   AACPI suggests that any proposed legislation extend the protections granted to physicians to all other healthcare professionals who may legally prescribe medications for the treatment of pain.

6) Treatment of individuals using drugs for nontherapeutic purposes: Most IPTAs state that the protections provided to physicians by these statutes do not apply if; 1) the individual receiving treatment is also receiving treatment for chemical dependence, or 2) the individual "is known, or should be known, to be using drugs for nontherapeutic purposes." The most recent IPTA goes one step further, specifically prohibiting physicians from prescribing controlled substances to these individuals. The use of opioids to treat pain in individuals with a present or past history of substance abuse is a complex and controversial subject. However, organizations that have produced statements of patients' rights with respect to pain treatment are in agreement with the Joint Commission on Accreditation of Healthcare Organizations, which states, "ALL patients have the right to the appropriate assessment and management of pain" *(emphasis added)*. [4] The American Society of Pain Management Nurses states, "healthcare professionals [are obliged] to manage pain and provide humane care to all patients, including those patients known or suspected to have addictive disease." [5] Policy statements from the American Society of Addiction Medicine recognize that these individuals present a number of challenges when they experience pain that can only be relieved with opioids, but that they nonetheless can and should receive such treatment if it is medically appropriate. [6] In addition, the term "using drugs for nontherapeutic purposes" is rather ambiguous, and certainly subject to a wide range of interpretations by individuals who may have disparate opinions about opioids. Curiously, none of the IPTAs attempts to further define this phrase; thus physicians are judged on the basis of unclear criteria.

   AACPI suggests that any proposed legislation avoid limiting the rights of individuals with current or past histories of substance abuse to receive appropriate treatment for pain, even if opioids must be used. Individuals with these disorders should be viewed as having a concurrent illness that requires a degree of expertise for its management, and they should not forfeit their right to pain control because of this concurrent illness.

In general, the AACPI strongly encourages individual State Pain Initiatives to use the legislative process very judiciously. In most cases, public policy barriers to good pain management can be overcome more efficiently and effectively by working closely with regulatory and licensing agencies within the various states. The legislative process, while powerful and enduring, presents the opportunity for a vast array of unintended consequences over which pain management advocates may have very little influence. Although the intended goal of IPTAs is laudable, the AACPI strongly recommends that State Pain Initiatives and pain advocates pursue non-legislative alternatives in order to achieve the goal of protecting healthcare professionals. For example, State Pain Initiatives should work with state health professional licensing boards, public officials, and law enforcement agencies to promote adoption of the Federation of State Medical Boards' *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain,* to engage in jointly sponsored educational sessions, to improve communication between health care professionals and state regulatory boards and agencies. Working directly with the state authorities from whom IPTAs attempt to protect physicians is likely to be a much more fruitful and effective strategy.

References

[1] University of Wisconsin Pain and Policy Studies Group (2003). Database of State Laws, Regulations, and Other Official Governmental Policies. Retrieved June 4, 2003, from http://www.medsch.wisc.edu/painpolicy/matrix.htm

[2] Joranson DE, Gilson AM. (1997). State intractable pain policy: Current status. *APS Bulletin*, 7:7-9.

[3] Joranson DE, Gilson AM, Ryan KM, Maurer MA, Nischik JA, Nelson JM. (2000). *Achieving Balance in Federal and State Pain Policy: A Guide to Evaluation*. The Pain & Policy Studies Group, University of Wisconsin Comprehensive Cancer Center. Madison, WI.

[4] Joint Commission on Accreditation of Healthcare Organizations (JCAHO). Available at http://www.jcaho.org

[5] American Society of Pain Management Nurses. (2003). ASPMN position statement: Pain management in patients with addictive disease. Retrieved June 4, 2003, from http://www.aspmn.org/html/Psaddiction.htm

[6] American Society of Addiction Medicine. (1998). Public policy statement on the rights and responsibilities of physicians in the use of opioids for the treatment of pain. *Journal of Addictive Diseases*, 17:131-133.

Biological Basis of Chronic Pain and the Role of Opioid Therapy

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Neurobiology of Pain and Its Treatment with Opioids

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Pain Pathway – Descartes (1664)

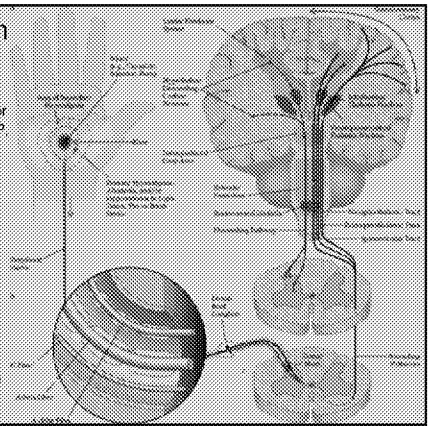
Medical School (1970)

- Straight wire with synapses
- Stimulus magnitude determines
  - Signal magnitude
  - Cortical response
  - Pain appreciation

Melzack, R., Wall, P.D.: Pain mechanisms: A new theory. Science, 150:971, 1965

Orientation

Nociceptors
Free nerve endings
Contain receptors for
BK, 5-HT, PGE, ATP,
H^+



Scientific American Medicine

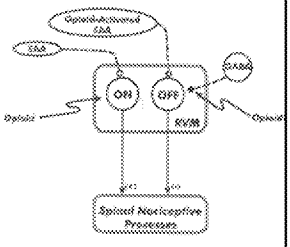
Types of Pain

- Nociceptive — High threshold
- Inflammatory — Spontaneous, low threshold
- Neuropathic — Spontaneous, low threshold
- Sensitization states — Spontaneous, low threshold

Pain System - Modes of Operation

- Normal – warns of harm
- Suppressed – permits function despite injury
- Sensitized – innocuous stimuli cause pain. Helps protect injured parts
- Reorganized
  - Represents true pathology of the system
  - Cells die, terminals degenerate, new terminals appear, synapses modified
  - Potentially irreversible

Descending Pain Facilitation / Inhibition

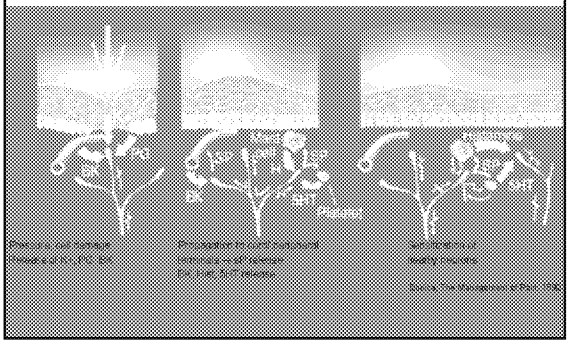


- Rostral Ventromedial Medulla (nucleus raphe magnus)
- On cells excite pain receptors
- Off cells inhibit pain receptors
- May generate pain signal with no peripheral stimulus
- Tasks requiring attention to nociception or to visual cues cause activation of on and off cells prior to pain stimulus.
- During opioid abstinence, on-cell firing markedly increases

Hyperalgesia

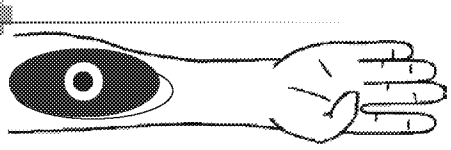
- Primary Hyperalgesia
  - Peripheral mechanisms
  - Inflammatory response
  - Involves increased sensitivity at the site of an injury
- Secondary hyperalgesia
  - Central mechanisms
  - Extends beyond the injury

Inflammatory Soup - Neurogenic Inflammation



Central Sensitization Secondary Hyperalgesia

Central Sensitization and Secondary Hyperalgesia Intradermal Capsaicin



- Primary zone
  - Static mechanical hyperalgesia
  - Thermal hyperalgesia - 1 hr
- Axon reflex flare
- Secondary zone
  - Dynamic mechanical hyperalgesia (allodynia)
  - 2 days
  - Light brush (A-β) → pain
  - Minor pinprick → hours of diffuse aching

Central Sensitization - Formalin Injection

- LA before formalin prevents hypersensitivity – no initial volley ⇒ no sensitization
- Opioids in low doses prevent sensitization. High doses required to block it.
- NMDA and NK-1 antagonists prevent hyperalgesia but do not block initial pain
- Conclusion:
  Initial pain barrage causes WDR sensitization, which causes most of the pain and hyperalgesia that follows injury

Central Sensitization – Significance:

- 3 d block of painful limb before amputation
  - ↓ phantom pain at 6 mo
- Amitriptyline during shingles
  - ↓ incidence of PHN
- 1200 mg gabapentin pre-mastectomy
  - ? postop pain, morphine requirement

  Dirks J, Anesthesiology 2002
- 300 mg gabapentin pre lap cholecystectomy
  - ? postoperative pain, analgesic requirement

  Pandey CK et al., Can J Anaesth. 2004
- May explain such paradoxes as cystitis pain after cystectomy

Visceral Hyperalgesia

- Symptoms previously considered psychogenic or due to anxiety
- IBS, noncardiac chest pain, nonulcer dyspepsia
  - From encoding innocuous stimuli as pain
- Multiple surgeries for "adhesions"
- Visceral hyperalgesia easier to elicit in genetically high anxiety rats

Gunter WD, et al. Physiol Behav 2000

Somatic Hyperalgesia?

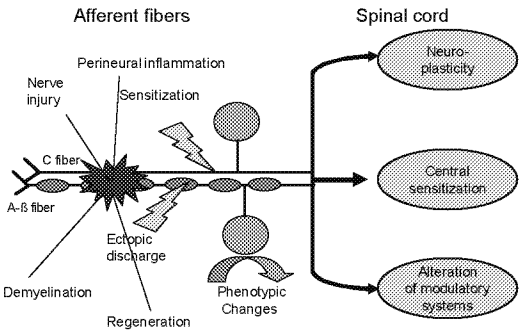
- Idiopathic CLBP, fibromyalgia
  - Thumb pressure, quantified
  - Patient report
  - fMRI
- Findings
  Both CLBP and fibromyalgia patients
  - Increased pain report vs. controls
  - Increased activation of pain-sensitive brain areas

Giesecke T, et al. Arthritis & Rheumatism 2004

Abnormal Input in Neuropathic Pain

- Deafferentation pain is usually not
- Lesions distal to soma leave a surviving (dys)functioning neuron
- Nerve transection, compression, demyelination, degeneration, or regeneration:
  - Insertion of "rapid-priming" Na+ channels
  - Spontaneous / ectopic discharge / mechanical sensitivity

Changes with Peripheral Nerve Injury



Woolf & Mannion, Lancet 1999
Attal & Bouhassira, Acta Neurol Scand 1999

Pain *Is* the Disease

- Peripheral nerve injury
  - sensitizes
- Dorsal horn
  - sensitizes
- Thalamus
  - sensitizes
- Cortex
- Evolving pathology

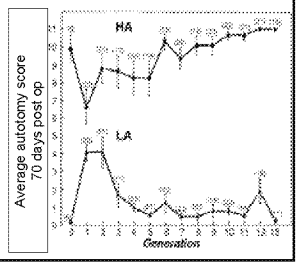
Essentials

- Pain changes the nervous system
  - Address it promptly
- Severe pain can be elicited by trivial stimulation or none at all
  - Sensitization
  - Neuroplasticity
- Psyche impacts pain as early as the DH
- Diagnostic enigmas
  - Looking in the wrong place, the wrong time

Wimps vs. Stoics?

Why Me?

- Why, after identical lesions, does one have crippling pain while another has no pain problem at all?
- Genetically isolated lines of rats showed high or low levels of autotomy following nerve injury
- Hybridization and backcross experiments showed that autotomy is transmitted by a single autosomal recessive gene.



Devor M, Raber P. Pain 1990

Genetic Polymorphism and Pain Perception

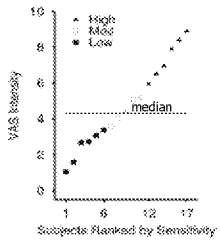
- COMT has a common genetic polymorphism
- Homozygotes for methionine at codon 158
  - ? μ-opioid system responses
  - ? sensory and affective ratings
  - ? negative affective state
- Opposite effects were observed in valine 158 homozygotes.
- Hetrozygotes were intermediate

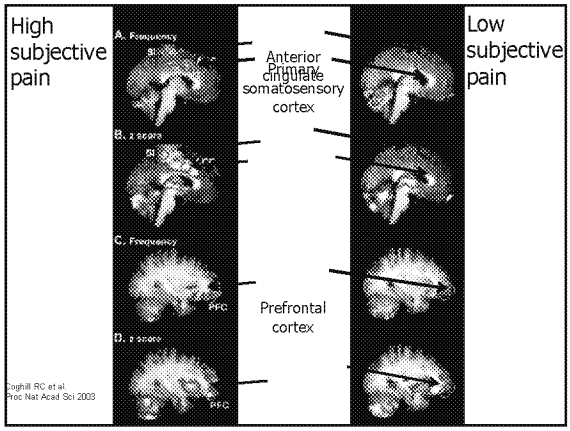
Zubieta, Jon-Kar et al., Science 2003; 299(5610); pp 1240-1243

Functional MRI vs. Subjective Pain Intensity

- Pain intensity ratings
- During functional MRI
- Subjective pain
- 49°C stimulus

Coghill RC et al. Proc Nat Acad Sci 2003





Implications

- Pain is just what the patient says it is?
- When incentives removed from the situation

Conclusions from Neurobiology

- The pain system involves many forms of modulation.
- The concept of chronic pain as an extension of acute nociception is not valid.
- Chronic pain is often an evolving process in which one pathogenic mechanism leads to others, so that the cause of pain changes over time.
- Pain perception is not simply a reflection of afferent input, but is a dynamic process influenced by past events.

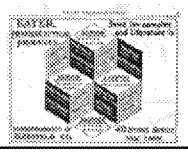
The Role of Opioids

Opioids in America

1800s –

Rx for pain, HA, asthenia, cough, diarrhea

1897



Opioids in America

- Waves of addiction led to
  - More cautious prescribing
  - Harrison Act (1914) – Established "controlled substances"
  - Excessive fears of opioid use

JAMA 1941

"The use of narcotics in the terminal cancer [patient] is to be condemned if it can possibly be avoided.
Morphine usage is an unpleasant experience to the majority of human subjects because of undesirable side effects. Dominant in the list of these ... is addiction."

Lee LE. Medication in the control of pain in terminal cancer. JAMA, 116(3): 216-220, 1941

Changing Attitudes / Expectations

- From oncology
  - Opioids have almost no ceiling
  - 90% of cancer pain controlled with simple opioids, usually p.o.
  - Good analgesia expected in cancer
- Post operative pain management services
  - Nearly pain free recovery
  - Expectation of pain control

Addiction in Acute Pain

- 11,882 inpts given narcotics for medical problems
  - None had a CD history
  - 4 subsequently abused drugs
  - This was a major problem only in 1

Porter J, Jick H, NEJM 302(2). 1980

- 10,000 burn patients
  - Frequent opioids, usually parenteral, protracted
  - No iatrogenic dependence
  - 22 subsequently abused drugs
  - All had previously done so

Perry, Heidrich:Pain 1982

Better Understanding of Addiction

- What it is:
  - Loss of control
  - Preoccupation, craving, compulsive
  - Use despite consequences
    - Behavioral
    - Medical
    - Vocational
    - Social
    - Legal
- Not:
  - Tolerance / withdrawal / quantity

Acute Pain Consensus

- Iatrogenic addiction in treatment of acute pain is rare
- The appropriate opioid dose for postoperative /post traumatic pain is whatever it takes

Acute and Cancer Pain Undertreated

- Poor understanding
  - pharmacology
  - pharmacokinetics
- Failure to ask patients re pain
- Fear of creating addiction – even in terminal patients
- Regulatory fears

Pain

- The 5th Vital Sign
- JCAHO Standards

Uncontrolled Pain Remains a Problem

- … an enormous public health problem in the United States.
- … devastating impact on physical, emotional, social, and economic well-being …

Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel
DEA, Last Acts, Pain & Policy Studies Group 2004

Chronic Non-malignant Pain

- Opioids historically avoided due to fears of:
  - Declining efficacy
  - Dose escalation
  - Impaired cognition, alertness, motor function
  - Promoting regression
  - Addiction

1992 Survey of State Medical Board Members Opinion on Opioid Use

	Lawful, generally acceptable	Lawful, generally not acceptable - discourage	Prob violation of med practice laws / regs - investigate	Prob violation of fed / state laws; investigate
Ca pain	75%	14%	5%	5%
Ca pain + hx opioid abuse	46%	22%	14%	12%
CNMP	12%	47%	32%	27%
CNMP + hx opioid abuse	1%	25%	58%	50%

Joranson DE, et al. Federation Bulletin 1992

Beginning of Liberalization

SCIENTIFIC AMERICAN February 1990 Volume 262 Number 2

The Tragedy of Needless Pain

Contrary to popular belief, the author says, morphine taken solely to control pain is not addictive. Yet patients worldwide continue to be undertreated and to suffer unnecessary agony

by Ronald Melzack

Beginning of Liberalization

- People suffer not because their discomfort is untreatable but because physicians are reluctant to prescribe morphine.
- Afraid of turning patients into addicts, they deliver amounts that are too small and too infrequent.
- When patients take morphine for pain, addiction is rare.
- Addiction seems to arise only in those who take it for psychological effects, e.g., euphoria or to relieve tension.
- Patients who take morphine for pain do not develop the rapid tolerance that is often a sign of addiction.

Melzack: Scientific American, 1990

Evidence Supporting Opioids in Nonmalignant Pain

- Numerous reports, some controlled studies, mostly 3-12 months
- Compellingly demonstrated
  - Opioids are effective for almost all forms of CNMP
    - Exception: deafferentation/post stroke?
  - The risk of addiction is remarkably low
  - Toxicity, except in OD, is a non-issue

Legal, Regulatory Pressures Reversed

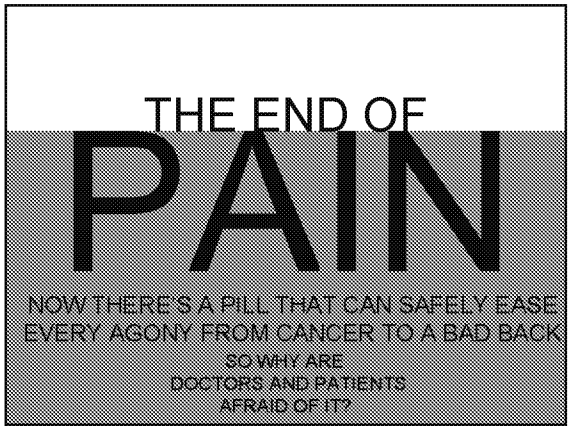
- "Pain Patients' Bill of Rights" - California
  - Frees physicians to prescribe any dose of opioids they consider appropriate
  - Requires that opioid maintenance not be relegated to "after all else fails"
  - Requires physicians who do not prescribe opioids for chronic pain to notify the patient of physicians who will
- Litigation for pain undertreatment
  - Oregon
  - California

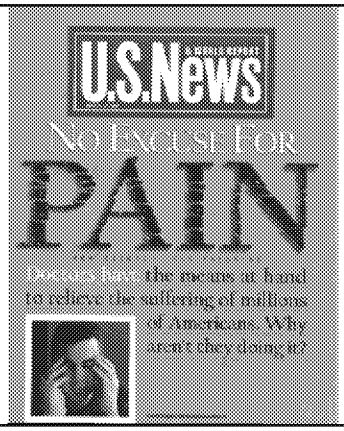
So Why Is There Controversy?

- Residual "opiophobia"
- Ambiguous, misunderstood regulations
- Clinical experience discordant with literature
- Dearth of long term data
  - Efficacy
  - Addiction risk
- Overzealous advocacy
- Unrealistic expectations
- Societal complications

The Pendulum Swings

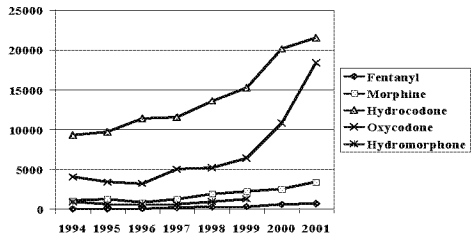
- Enthusiasm for chronic opioid therapy grew rapidly
- The condemnation of opioids was, in many places, replaced with unbridled enthusiasm
- Unrealistic expectations developed





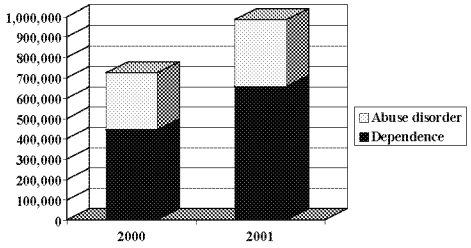
The Down Side

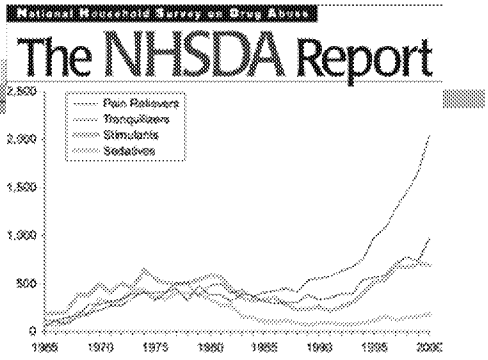
DAWN Data – ED Mentions



National Household Survey on Drug Abuse

Prescription Abuse Disorder / Dependence
DSM-IV Criteria





Annual Numbers of New Nonmedical Users of Prescription-Type Drugs, by Drug Category: 1965–2000

Data May Promote Erroneous Conclusions

- Abuse of prescription drugs ? abuse of prescribed drugs
  - "Borrowed" from relatives, friends
  - Pharmacy robberies
  - Rx forgery
- Lack of information creates uncertainty re the role of inappropriate prescribing as a cause of the problem

"Iatrogenic Addiction" – Not Always Iatrogenic

- N = 48 hospitalized for addiction to OxyContin
- Retrospective study
- 77.1% reported prior non-opioid substance use problems
- 15 (31%) began Oxc via legitimate rx
- In comparison with "illicit" users:
  - None had prior opioid misuse
  - More likely to have prior detox (unknown from what)
  - More likely to have early onset alcohol and illicit drug use

Conclusion

- Prior substance abuse is common among patients with addiction to OxyContin

Potter JS et al., Drug and Alcohol Dependence, 2004

Where Are We Now?

Issues:

- There is much that we do not know about
  - Addiction
  - Chronic pain
  - Efficacy of decades of opioid analgesia
- We can't delay care until we find out

Start with What We Know

The relief of suffering is universally acknowledged as a cardinal goal of the ethical and compassionate practice of medicine.

AMA Council on Scientific Affairs

Medical Issues in Opioid Maintenance

- Potential benefits
  - Analgesia
  - Function
  - Quality of life
- Risks
  - Toxicity
  - Functional impairment
  - Addiction/physical dependence
  - Hyperalgesia

Opioid Risks

- Organ toxicity – essentially nil
- ? prolactin, ↓ cortisol, LH, FSH, testosterone, estrogen

  Ballantyne & Mao: NEJM 2003
- Alter immune cells, ?immunosuppression in HIV

  Rahim RT et al. J Neuroimmunol. 2002
- Overdose – lethal
  - Especially combined with other drugs
- Functional impairment
- Tolerance / hyperalgesia
- Abuse / trafficking

Opioid Induced Impairment

- Methadone maintenance
  - Minimal functional impairment
  - Safe to drive, work
- Cancer
  - Transient impairment after dose ?
  - Residual - slowing > errors
- Options
  - Benzodiazepines, AEDs, antidepressants may impair function
  - Unrelieved pain impairs cognition

Acute Efficacy

- Not all pains are equally opioid responsive
- More responsive
  - Dull, aching, visceral pains
- Less responsive
  - Neuropathic, esp. deafferentation
  - Skin
  - Sharp pain
  - Incident pain

Chronic Efficacy

- Cancer
  - Opioid requirements generally stable until disease progression
- CNMP
  - Most report several weeks' dose titration, then stability for months – years
- Methadone maintenance
  - No analgesia for acute pain

Maintenance Opioids in Addicts

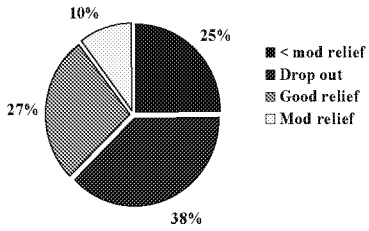
- N = 20
- CNMP + history of substance abuse
- Patients treated for > 1 year
- Those who abused treatment did so early.
- Non-abusers
  - more likely to be active in AA
  - stable support systems.
  - less likely to be recent polysubstance abusers

Dunbar SA, Katz NP. J Pain & Symptom Mgt , 1996

Conflicting information

Transdermal Fentanyl in Neuropathic Pain

- Open study
- N = 48
- 12 wk trial
- Neuropathic pain
- 63% failed or dropped out



Dellemijn PL, et al. J Pain Symptom Manage. 1998

COT – Most Benefit is Transient

- 9 wk, randomized, crossover
  - Musculoskeletal, rheumatic pain
  - Excluded: substance abuse, depression, neuropathic pain, headache
- Morphine = 60 mg bid vs. placebo
- Initial:
  - MS ? substantial pain reduction
- Late:
  - Small pain reduction
  - No change in function (on 4 instruments)

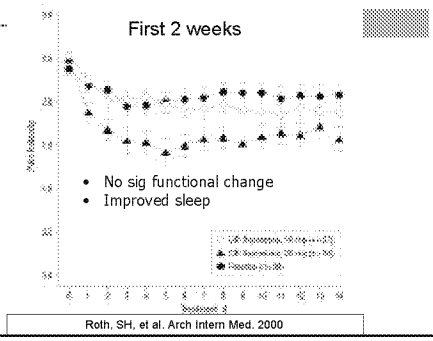
Moulin DE et al, Lancet 347:143-7, 1996

SR Oxycodone in Osteoarthritis

- N= 133 rheum clinic pts, pain ≥ 1 month
- 61% using opioids at study entry
- PBO vs. Oxc 10 bid vs. Oxc 20 bid
- Pain scale = 0 – 3 (3 = severe)
- 14 d trial – 49% dropout

Roth, SH, et al. Arch Intern Med. 2000

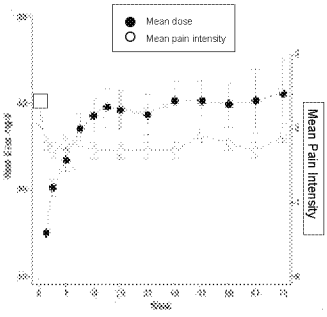
SR Oxycodone in Osteoarthritis



Roth, SH, et al. Arch Intern Med. 2000

SR Oxycodone in Osteoarthritis

- 6 mo extension (n = 106)
- 12 mo extension
- 57% dropout
- Baseline pain 2.4
- Last year pain 1.7-1.9
- My math: Pain 8 ? 6.3/10



Roth, SH, et al. Arch Intern Med. 2000

Daily Scheduled Opioids for Intractable Headache

- N = 160
- 70 remained on DSO = 3 years
- 26% of 160 with >50% improvement
- 74% – no significant improvement or discontinued for clinical reasons
- Problem behavior in 50%
  - Rarely required stopping opioids

Saper, JR, et al. Neurology 2004

Daily Scheduled Opioids for Intractable Headache

- Family often revealed contradictions between the patient's strong belief that drugs were helping vs the family's deep concern about lack of functional improvement or adverse effects displayed at home but not in the center.
- Several patients discontinued DSO under protest, remained in non-opioid treatment, later were very glad to be off opioids. In retrospect they described anhedonia / amotivational state while taking opioids. During opioid treatment they did not recognize their compromised status and often embellished the extent to which opioids were helping.

Saper, JR, et al. Neurology 2004

Opioid Therapy for Chronic Pain
Review

- Virtually all studies on the long-term (> I yr) opioid analgesia are surveys / case series
- These studies suggest
  - "Satisfactory analgesia" can be achieved with a stable dose of < 195 mg/d morphine equivalents
  - Cognitive and mechanical function are preserved
  - Addiction risk is low
- They do not provide evidence about long-term efficacy
- Abuse and diversion are best detected by adhering to prescribing guidelines. Noncompliant patients are most likely to abuse or divert.
- High-dose, prolonged opioid therapy may be unsafe, ineffective, or both, and is to be avoided.

Ballantyne & Mao, NEJM 2003

Opioid Cessation May Reduce Pain

- CD unit rx, 50 CNMP pts
  - 32 had improved pain, work, family relationships, sex function

Finlayson RE, et al, Pain, 1986

- Detoxification, relaxation training, 3 session therapy
  - ↓ pain

Taylor CMB, et al, Pain 8, 1980

- Detoxification, n = 4 CNMP pts: ↓ pain, return to work

Brodner RA, Taub a, Mt Sinai Med J 45, 1978

- 200 mixed HA patients
  - Prophylaxis most effective in those weaned from opioids

Kudrow L, Adv Neurol 33, 1982

Confounder – Satisfaction ≠ Success

- Intrathecal opioids, n = 38
- Mean Rx = 50 months
- Objective outcome:
  - Dose escalation: 6 - fold
  - Persistent high pain levels – small decrease
  - Severe disability per Oswestry
  - Multiple side effects, system complications
  - Lower health-related quality of life than RA
  - Physical function < CHF

Brown, Klapow, Doleys,. Clin J Pain 1999

Confounder – Satisfaction ≠ Success

Subjective (retrospective) outcome

- Family
  - 61% pain improvement
- Patients
  - 64% pain improvement
  - 48% improvement in function.
  - 81% good to excellent satisfaction

Brown J, Klapow J, Doleys D, et al. Clin J Pain 1999

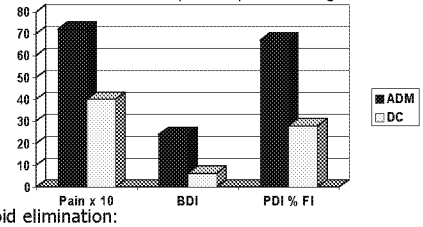
Chronic Pain Rehabilitation Program with Opioid Wean

Our Data

- 1 year sample
- 228 consecutive admissions
- 56 taking ≥ 100 mg p.o. morphine equivalents/d on admission
- 5 dropped out within 3 days
- 5 no outcome data (drop outs, dismissals)
- Data on 46

Chronic Pain Rehabilitation Program with Opioid Wean

Mean admission morphine equiv = 457 mg/d



After opioid elimination:

- 3 had increased pain
- 42 had pain reduction

Opioids as a Cause of Pain

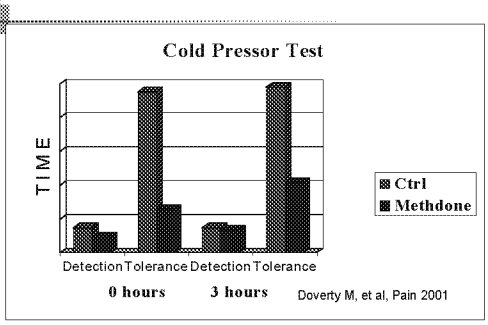
- Spinal dynorphin produced in response to sustained opioid exposure is pronociceptive
  - The descending facilitatory tract is the probable source of this opioid induced hyperalgesia

Vanderah TW, et al. Pain 2001
Vanderah TW et al. J. Neuroscience 2001

- Neurophysiologic changes after chronic opioids are similar to those in hyperalgesia/sensitization
- Opioid tolerant rats are hyperalgesic

Mao J, Price DD, Mayer DJ. Pain 62 (1995) 259-274

Hyperalgesia in Methadone Maintenance



Doverty M, et al, Pain 2001

Clinical Strategy in the Face of Ambiguity

Consider three constituencies

- Patient
- Society
- Physicians

The Federation of State Medical Boards Model Policy is an excellent, common sense start.

Model Policy for the Use of Controlled Substances for the Treatment of Pain

- Notwithstanding progress to date … both acute and chronic pain continue to be undertreated.
- The … board recognizes that the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

Federation of State Medical Boards of the US, Inc. May 2004
http://www.fsmb.org/

Taking Care of the Patient

- Risk/benefit assessment
  - Opioid responsive pain?
  - Physiologic exam?
  - Addiction vulnerability
    - Family, personal history
  - Reliable patient?
- Clear plan, objectives
  - Opioids are to have a life, not to hide from life.
- Opioids - often necessary, rarely sufficient
  - PT, other medications, counseling, relaxation training

Drug Choice

- Fast in / out – most addicting
  - Nicotine, cocaine, heroin, barbiturates
- Slow onset / long acting
  - SR preparations
  - Methadone
  - Buprenorphine?
- Avoid toxic metabolites
  - Meperidine, propoxyphene
- Avoid mixed agonist-antagonists
  - Therapeutic ceilings, psychotomimetic, mostly IM
- Change drugs when one is/becomes ineffective
  - Individual variability, incomplete cross tolerance

Outcome Monitoring is Essential

- Analgesia – pain level – 0 -10
- Affect – Beck Depression Inventory, Zung, Ham-D
- Activity level – Pain Disability Index, Oswestry
- Adverse effects – cognition, alertness
- Aberrant behaviors – multisourcing, lost drugs

If not effective,

Red Flags for Abuse
Require Intervention

- Lost / stolen prescriptions
- Early refills
- Multisourcing
- Use for psychoactive effect
  - Suggested by rapid escalation
  - It is likely that desired psychoactive effect requires intoxication, and tolerance to this develops quickly, in contrast to analgesia.

Protecting Society

- Diversion is a serious concern
- Physicians are not detectives, but should not be naïve
- Chronic pain patients are often poor
- Street value >>> legitimate price
- A patient convicted of diversion should obtain opioids from methadone centers, if at all
- Toxicology screen (GC/MS) should be positive. If not, consider diversion, or false sample to conceal other drugs

Be Financially Responsible

- Prolonged high dose opioids can be costly
  - Expensive analgesics are no more effective, ± more convenient
  - $30/mo methadone ˜ $450/mo branded SR drugs
- IV infusions, pumps, intrathecal agents
  - Mostly useful in acute pain and terminal care
  - Short gut, emesis, impaired consciousness, impaired swallowing
- Most opioids are well absorbed sublingually, rectally, vaginally

Protect the Physician

- Document
  - Sufficient work-up to establish diagnosis
  - Decision making process
  - "Contract"
    - Written description of risks
    - Informed consent
    - Patient's agreement to responsible use and accountability
- Patients must be held accountable.

Conclusions – Acute, Cancer Pain

- Acute, cancer, AIDS pain are undertreated.
  - The goal is comfort.
  - Failure to treat acute pain may predispose to chronic pain.
- It is rare for acute opioids to cause addiction where none existed (though patients switch substances.)
- The risk of addictive relapse is unstudied Patients in recovery need special care

Conclusions – Opioid Efficacy in Chronic Nonmalignant Pain

- Opioids do not eliminate CNMP
  - 35% mean lasting reduction is a positive study
  - Increased function is a success
- Response varies
  - Some have ? quality of life, ? suffering, ? function
  - Others deteriorate
  - It is difficult to predict outcome
  - But - less helpful if "abnormal illness behavior"
- Efficacy of years of treatment is unknown

Conclusions – Iatrogenic Addiction

- The risk of new addiction with chronic opioids is unclear, apparently low.
- The risk of addictive relapse is unstudied
- A closely monitored trial with accountability is low risk, if not continued beyond the point of failure.

Future Predictions

- The appropriate role of opioids in CNMP will be revealed by our current massive social experiment
- Research may produce
  - ways to prevent / reverse tolerance (NMDA, IL antagonists)
  - alternative opioids with minimal cross tolerance
- Predictions:
  - Chronic Opioid Therapy will be established as an important treatment for chronic pain
  - It will help many for a number of years
  - It will fail many after a number of years
  - It will not be the answer for more than a few

Regulatory Responses to Abuse and Diversion

Presented by:

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Regulatory Response to Abuse and Diversion

Federation of State Medical Boards
Boston, Massachusetts
April 7-8, 2005

June L. Dahl, PhD
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Dahl 2005

Significant increase in interest in PMPs

Use existing information sources before establishing a prescription monitoring program

Dahl 2005

If a PMP is being considered:

- Avoid use of government-issued single-copy serialized prescription forms
- Include all controlled substances, II through V, not just Schedule II drugs
- Administer the program through a health care rather than a law enforcement agency

Dahl 2005

PMPs: Recommendations for Consideration

- **Use a medical review group to protect legitimate prescribing and dispensing**
  - Supervise management and use of the data
  - Develop and review mechanisms to facilitate targeting of suspicious practices
  - Review prescribing practices
  - Review individual patient data
  - Oversee annual data-based performance reports

Dahl 2006

PMPs: Recommendations for Consideration

- **Protect patient confidentiality to the greatest extent possible**
- **Give healthcare professionals access to PMP data**
- **Give law enforcement access to the data when justified by probable cause**

Dahl 2006

PMPs: Recommendations for Consideration

- **Encourage research to evaluate the impact of the programs on patients who need controlled substances for legitimate medical purposes and on the problem of drug diversion and abuse in the state**
- **Such an approach is essential to maintaining balance**

Dahl 2006

PMPs: Recommendations for Consideration

- Sponsor educational programs
- Encourage healthcare professionals to communicate with PMP administrators

Dahl 2005

Responding to Diversion

Federation of State Medical Boards of the US
Boston, Massachusetts
April 2005

Pain & Policy Studies Group
University of Wisconsin Medical School
World Health Organization Collaborating Center
www.medsch.wisc.edu/painpolicy

Consequences of diversion

- Illicit availability of prescription drugs
- Crime
- Misuse, abuse, addiction
- Morbidity and mortality
- Reduced confidence in medications
- Reluctance to prescribe
- Reduced patient access to care

Media Coverage about pain and the war on drugs

The War on Painkillers
New York Times 29 Jan 2002

A War on Drugs or a War on Healing?
Tallahassee Democrat 5 Jan 2004

Painkillers: The New Villain in the Drug War
Atlanta Journal Constitution 6 Jan 2004

Doctors Cautious with Pain Prescriptions
Roanoke Times 23 May 2004

Doctors: Patient Care Losing to War on Drugs
Decatur Daily 26 Oct 2003

Laws Intruding on Medicine Do Little for Patients Redding Record Searchlight 1 Aug 2004

Types of diversion

- **Internal:** By registrants and agents in the system
  - ✓ Physicians, Pharmacists, Nurses
  - ✓ Employees
  - ✓ Patients
- **External:** Attacks on the system by non registrants
  - ✓ *Theft, armed robbery: distributors, carriers, pharmacies, hospitals
  - ✓ Forgery
  - ✓ Shoppers
  - ✓ Internet

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A public health response to diversion

- Understand the entire problem
- Identify all sources "vectors"
- Use existing information to measure
- Prioritize according to severity
- Plan interventions
- Use appropriate authority
- Avoid unintended consequences
- Evaluate outcomes

Are we there yet?

A "Balanced" response to diversion

- Opioids safe and effective, necessary
- Potential for abuse, control system
- "Controlled substance" does not change medical value of approved drugs
- Policy governing drugs and professional practice should not conflict with medicine
- Efforts to address diversion must not interfere with medical practice and patient care

Do we have a balanced approach?

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Recognition of the principle of Balance

- Institute of Medicine
- American Cancer Society
- National Cancer Institute
- Federation of State Medical Boards
- American Medical Association

- International Narcotics Control Board
- World Health Organization
- European Union

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Balancing roles of clinicians and law enf.

	CLINICIANS	LAW ENF./REG.
Primary	• Evaluate patients' pain • Relieve pain	• Evaluate sources of diversion • Stop diverters
Secondary	• Know about diversion • Avoid contributing to diversion	• Know about pain management • Avoid interfering in medicine and patient care

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Outcomes of a "balanced" approach

- Sources of diversion are identified and resolved
- No interference in medical practice or patient care

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How to achieve balanced outcomes?

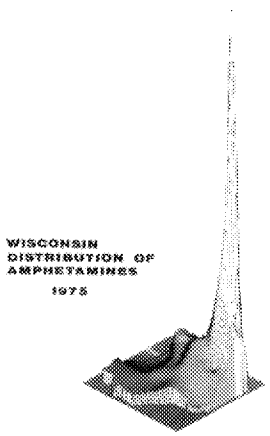
1. Identify sources
   - Medicaid, pharmacy theft, PMP, ARCOS, Drug evidence, ER data, etc
   - Identify potential targets; inquiry, investigation
2. Intervene
   - Educate, treat, decertify, lock-in, discipline, criminal
   - Proportionate responses
   - Avoid sensationalism
3. Coordinate
   - Diversion prevention and control program
   - Uniform Controlled Substances Act
4. Evaluate

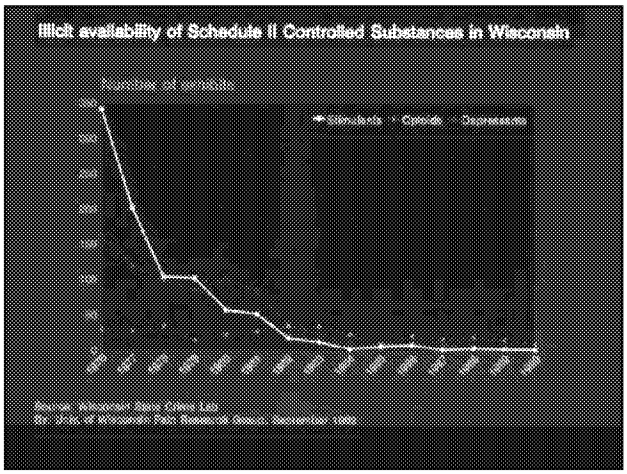
Are we doing this?

1. 1980 Congress amends the Controlled Substances Act

"The Attorney General shall annually select the controlled substances in Schedule II which have the highest rate of abuse and prepare and make available to regulatory, licensing, and law enforcement agencies of States descriptive and analytic reports on the actual distribution patterns in such States…"

Which agency in your state uses these data to target diversion?





2. 1984 Congress amends the Controlled Substances Act

1984:	Pharmacy theft becomes a federal crime; DEA 106 form
2002:	> 45 pharmacy thefts in Boston area
2000-03:	2,494 thefts of Oxycontin, 631 armed robberies, 707 night break-ins; 1,369,667 dosage units diverted
2004:	Theft of 2 shipments of 140,000 Roxicet tablets
2004:	"the number of pharmacies reporting drug losses due to breaking and entering has increased."

Who investigates pharmacy crimes in your state?

3. US GAO Recommendations to address diversion in state Medicaid

1983 "Prescription Drug Abuse and Diversion in the Medicaid Program"

1988 "Controlled Substances: Medicaid Data May Be Useful for Monitoring Diversion"

1997"States Can Readily Identify Illegal Sales and Use of Controlled Substances"

Does your state use Medicaid data?

Balanced Approaches

- Stop internet availability of opioids
- Identify perpetrators of pharmacy crime
- Improve clinicians' assessment of risk*
- Identify doctor-shoppers*
- Identify prescribers and dispensers who divert*
- Expand drug abuse education & treatment

Are we doing this?

* Requires up to date knowledge of pain and addiction

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Unbalanced approaches

- Don't stock it
- Reduce the dose
- Stop prescribing
- Refer pain patients to specialists
- Contracts and urinalysis for all patients
- Sensational coverage of physician arrests

Are we doing this?

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Unbalanced approaches lead to…

- Increased patient fears
- Decreased physician willingness to prescribe
- Decreased patient access to pain relief

and…

- <u>The actual sources of diversion may not be addressed</u>

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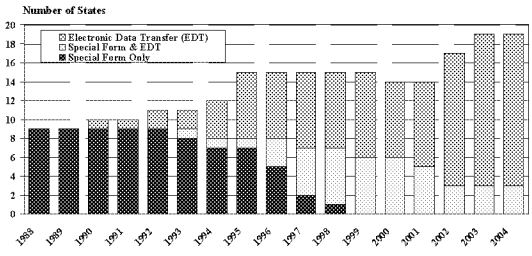
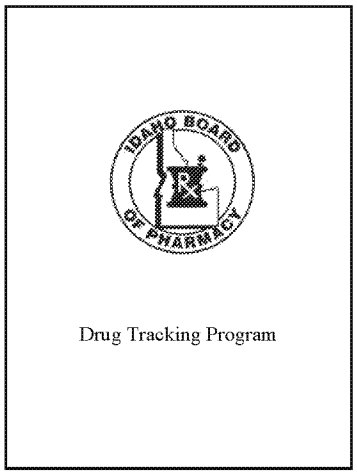
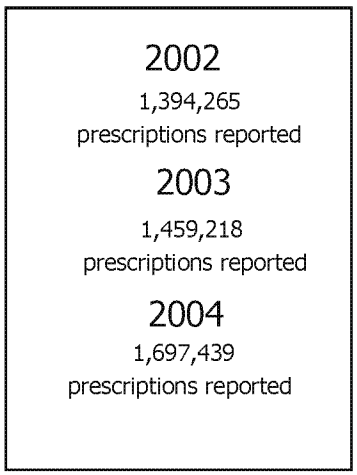
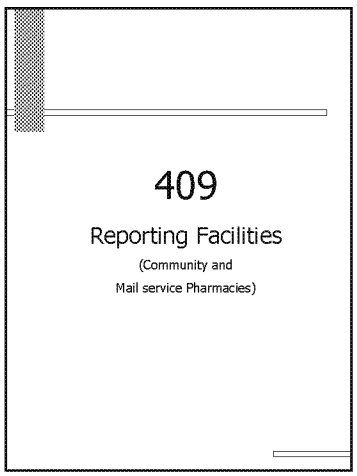
Trend in State Prescription Monitoring Programs



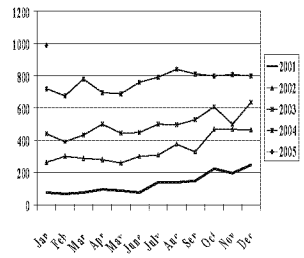
Notes: (1) Trend is based on year legislation was adopted. (2) "Special form" may be single-copy, duplicate, or triplicate.
Source: LEXIS; U.S. Drug Enforcement Administration "Prescription Accountability Resource Guide" September 1998; U.S. General Accounting Office "Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion" May 2002, and updated information obtained from states.
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2004.


IDAHO BOARD OF PHARMACY
Drug Tracking Program


2002
1,394,265
prescriptions reported
2003
1,459,218
prescriptions reported
2004
1,697,439
prescriptions reported


409
Reporting Facilities
(Community and
Mail service Pharmacies)

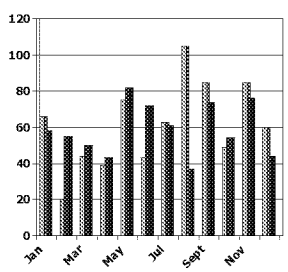
Number of Profile Requests

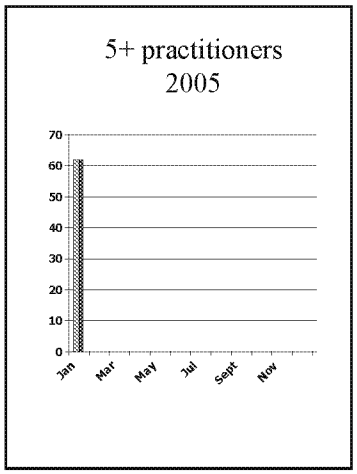


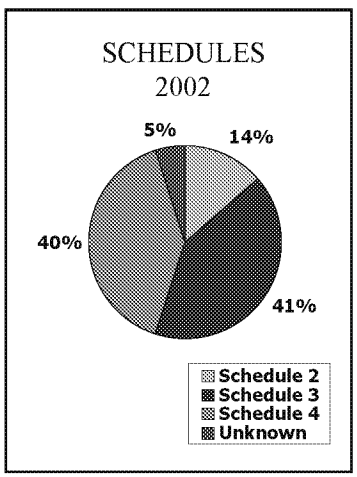
Requests from

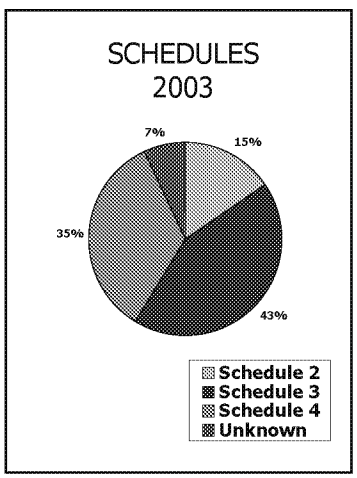
Practitioners
Law Enforcement
Other State Agencies
Pharmacies

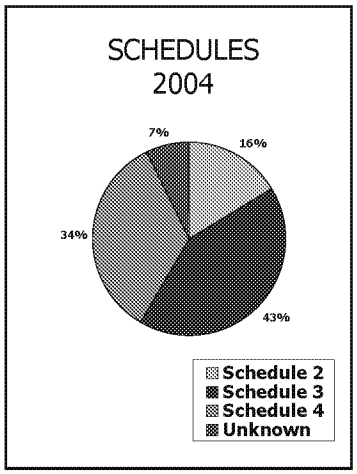
5+ practitioners 2003/2004

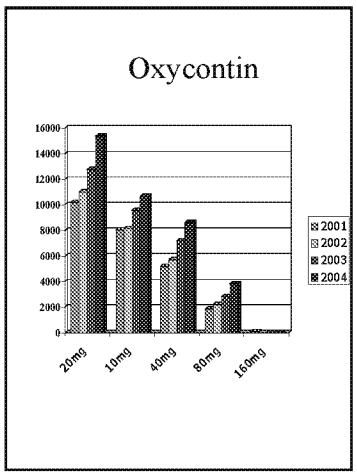


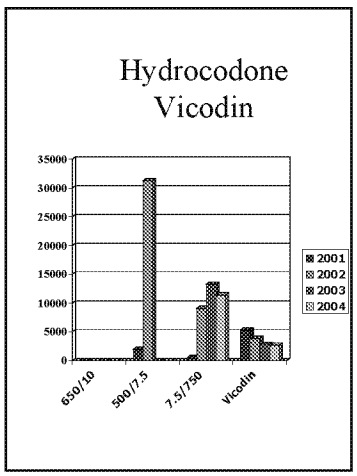

5+ practitioners
2005
70
60
50
40
30
20
10
0
Jan
Mar
May
Jul
Sept
Nov


SCHEDULES
2002
5%
14%
40%
41%
Schedule 2
Schedule 3
Schedule 4
Unknown

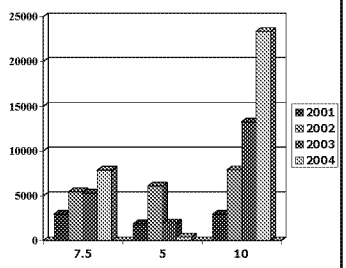

SCHEDULES
2003
7%
15%
35%
43%
Schedule 2
Schedule 3
Schedule 4
Unknown


SCHEDULES
2004
7%
16%
34%
43%
Schedule 2
Schedule 3
Schedule 4
Unknown

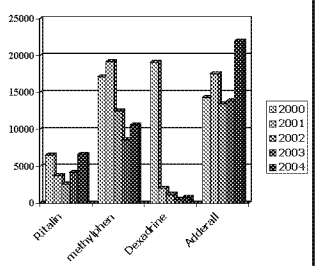

Oxycontin
16000
14000
12000
10000
8000
6000
4000
2000
0
20mg
10mg
40mg
80mg
160mg
2001
2002
2003
2004


Hydrocodone
Vicodin
35000
30000
25000
20000
15000
10000
5000
0
650/10
500/7.5
7.5/750
Vicodin
2001
2002
2003
2004

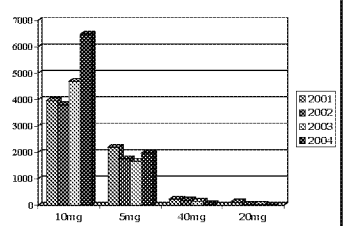
Norco



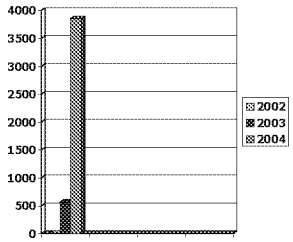
Dexedrine/Ritalin/ Adderall



Methadone



AVINZA



Program Costs

Employee costs	$140,000
Maintenance	$ 6,000
Miscellaneous costs	$ 1,751
TOTAL	$147,751

Kentucky Board of Medical Licensure Experience with KASPER

KASPER – Kentucky All Schedule Prescription Electronic Reporting

Background

- Program implemented effective 1/01/1999;
- Responsible for collecting the dispensing of Schedule II-V Drugs by Pharmacies, Dispensing Physicians, Vets, or other Kentucky licensed dispensers
- Oversight provided by KY Drug Enforcement Branch;

Investigations Prior to KASPER

Sources of Grievances

- Primarily grievances came from pharmacies;
- Drug Control Branch would provide referrals;
- Public

Investigations Prior to KASPER

Investigative Process

- Canvassing of multiple pharmacies;
- Enlisting the assistance of law enforcement & other Board investigators;
- Accumulating paper records of scripts;
- Hand tabulation of information collected and submission to Drug Control for analysis;

Investigations Prior to KASPER

Problems with the process

- Man hours and resources – caused a limited number of grievances to be investigated;
- Initial decision had to be made on how large a net to cast – number of pharmacies and cities to be included;
- Major disruption in the day-to-day operations of pharmacies;
- Accuracy of Information Collected;

KASPER – A Quantum Leap Forward

A dispenser of a Schedule II, III, IV or V controlled substance must transmit the following data within 16 days of the date of the dispensing:

- Patient identifier
- National drug code of drug dispensed
- Metric quantity of drug dispensed
- Date of dispensing
- Estimated days supply dispensed
- DEA registration number
- Prescriber information

Limitations to KASPER Statute

- Drugs directly dispensed or administered by doctor not covered
- Felony for unauthorized receipt or disclosure
  - Questions about discovery report;
  - Questions about specific testimony about report;
  - Questions about admissibility of report;
  - Report cannot be shared with law enforcement or other agency;
  - Statute indicates any of these actions require Court order;

KASPER – Kentucky All Schedule Prescription Electronic Reporting

Background

- Drug Control is responsible for reviewing and analyzing all data collected from the program. This review may identify potential cases of drug over-utilization, misuse, or over prescribing for referral to appropriate practitioners, law enforcement agencies, professional licensing boards and other state agencies.

KASPER – A Quantum Leap Forward

The Drug Control Branch may provide data to a licensing Board who is:

- Involved in a bona fide investigation; and
- Involving a designated physician;

Overall Benefits of KASPER

Benefits for the KBML

- Provides a comprehensive analysis of physician prescribing;
- Provides a focused consultant review;
- Allows the Board to be proactive rather than reactive in prescribing cases;

KASPER – Advantages to the KBML

Analysis of KASPER by Drug Control Pharmacy Investigators helps the Board:

- Identify specific problems and patterns;
- Identify specific patient charts for review by Board consultant/expert;

KASPER – Advantages to the KBML

- Allows Board to review more prescribing cases;
- Information is centrally located and easily accessed by investigators;
- Greater likelihood of complete and accurate prescribing information for specific doctor;
- Format makes it easier to spot trends;

KASPER – Advantages to the KBML

Assists Consultants in reviewing patient charts by:

- Giving the consultant a perspective on a physician's overall prescribing practices;
- Provides information not recorded in patient records;
  - Refill information not recorded in the patient record

KASPER – Advantages to the KBML

KASPER serves a valuable tool for physicians by:

- Preventing "doctor shopping" and diversion
- Provides information on past treatment that was not provided by patient;

Issues with KASPER

- Drastic increase in workload for Board;
- Increased workload for Board consultants;
- Volume of requests slows access;
- Pharmacy reporting errors;
  - Example – Script attributed to wrong physician;
- Computer errors – additional 0's to the actual scripts prescribed ;
  - Investigator must verify actual number of scripts;

Issues with KASPER

- Patients can go to border states to fill their prescriptions from Kentucky (7 Border States)
- Mail order prescriptions not always reported to KASPER;
- Internet prescribing is not reported to KASPER;

Competing Values Addressed in the Development of KASPER

- The Board's interest in complete and accurate investigative information;
- The Board's interest in easier & more organized access for its investigators;
- The State's interest for the Board to identify and stop diversion and risky drug use quickly;
- Concern about "Big Brother" oversight;
- Concerns of patient records, especially prescribing records;
- Concerns that system may deter effective pain control – "chilling effect".

The New KASPER – Another Leap Forward

In 2004, the Kentucky General Assembly expanded Drug Control's ability to provide KASPER information to the KBML. Now, the Board has the new authority to receive KASPER information for any physician who is:

- Associated in a business relationship with a physician who is already under investigation by the Board for improper prescribing practices;
- In a designated geographic area for which a trend report indicates a substantial likelihood that inappropriate prescribing may be occurring; or
- In a designated geographic area for which a report on another physician in that area indicates a substantial likelihood that inappropriate prescribing may be occurring in that area.

Future Challenges

- When to expand investigation to other physicians in practice;
- How to select geographic regions for KASPER review;
- Balance Board's responsibility to investigate with the need to prescribe appropriately for pain;